

OPEN MINUTES
Missouri Board of Pharmacy

April 5-6, 2016
Holiday Garden Inn
3300 Vandiver, Drive
Columbia, MO

The Missouri Board of Pharmacy met in open session during the times and dates stated in the following minutes. The regular meeting was called to order by President Christina Lindsay at approximately 8:02 a.m. on April 5, 2016, at Holiday Garden Inn, Columbia, Missouri. Each item in the minutes is listed in the order discussed.

Board Members Present

Christina Lindsay, R.Ph., President
Christian Tadrus, PharmD, Vice-President
Barbara Bilek, PharmD., Member
Douglas R. Lang, R.Ph., Member
Pamela Marshall, R.Ph., Member

Board Members Absent

Anita Parran, Public Member

Staff Present

Kimberly Grinston, Executive Director
Tom Glenski, R.Ph., Chief Inspector
Bennie Dean, R.Ph., Inspector
Katie DeBold, R.Ph., Inspector
Joe Dino, R.Ph., Inspector
Jennifer Luebbert, Compliance Coordinator
Andi Miller, PharmD, Inspector
Tammy Siebert, Administrative Coordinator
Lisa Thompson, R.Ph., Inspector
Dan Vandersand, R.Ph., Inspector
Elaina Wolzak, R.Ph., Inspector
Barbara Wood, R.Ph., Inspector

Others Present

Curtis Thompson, Legal Counsel

MOTION TO CLOSE 8:03 A.M.

At 8:03 a.m., Pamela Marshall made a motion, seconded by Christian Tadrus, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section

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610.021(1), (3), (5), (7), (13), (14), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 4:0:0:1 with roll call vote as follows:

Barbara Bilek – yes

Pamela Marshall – yes

Anita Parran – absent

Douglas Lang – yes

Christian Tadrus- yes

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT 8:03 AM

RETURN TO OPEN

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 9:04 a.m.

MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM AT 9:04 A.M

PRESIDENT LINDSAY CALLED THE OPEN SESSION MEETING TO ORDER AT APPROXIMATELY 9:09 A.M.

#A1 Agenda Additions/Corrections

Kimberly Grinston reported items # D4A, # D5A, # D6A, # D7A, # D8A, # D9A, # E4A, # E5A were added to the open session agenda.

#A2 Board Member Report

DISCUSSION: Christian Tadrus commented Kimberly Grinston gave a presentation at the Missouri Pharmacy Association's Legislative Day which Mr. Tadrus reported approximately 450 people attended. Ron Fitzwater, CEO of the Missouri Pharmacy Association, indicated there were multiple timely presentations and thanked the Board for its support.

#A3 General Administration Report

DISCUSSION: Kimberly Grinston provided the following updates:

- Technician Renewals: Technician renewal is currently underway; renewals must be submitted before May 31st.
- Financial Report: The Board's previously approved fee decreases for pharmacists and intern pharmacists will be effective in 2016. The technician renewal fee decrease will be effective in 2017. Due to delays in approval, the Board was unable to reduce technician fees for 2016.
- NABP Meeting: The NABP annual meeting will be held in May in San Diego; multiple board meetings will be attending.

- TALKOM Meeting: Ms. Grinston attended the meeting in Oklahoma and indicated a strong discussion between the states. Ms. Grinston reported Oklahoma's pharmacist inspector presented an interesting program on pharmacy ethics that may be beneficial for Missouri licensees. Ms. Grinston suggested the Board contract with Oklahoma to present a similar webinar in Missouri. **A motion was made by Pamela Marshall, seconded by Barbara Bilek, to pursue and approve the ethics program for 1.5 continuing education (CE) hours. Motion passed 4:0:0:1 with roll call vote as follows:**

**Barbara Bilek – yes Douglas Lang- yes Pamela Marshall – yes
Anita Parran – absent Christian Tadrus – yes**

- Pharmacy Diversion Conference: Ms. Grinston reported BNDD reported an increase in controlled substance diversion during the MPA annual meeting. Ms. Grinston indicated she talked with BNDD and asked if the Board would be interested in funding/sponsoring a diversion awareness conference for pharmacy licensees. Discussion was held. Barbara Bilek suggested meeting after office hours to increase attendance. Pamela Marshall suggested a Saturday conference which she reported was effective for the DEA. Douglas Lang suggested adding diversion prevention/awareness to strategic planning and noted the NADDI conference had a "tough love" presentation that may be beneficial. Mr. Lang also asked the office to contact BNDD to determine if there are any statistics on where the most diversion is occurring. Board consensus to proceed with planning the diversion conference. Ms. Grinston reported they may be able to develop a presentation by June/July.
- Suicide Prevention Week: Ms. Grinston indicated suicide prevention week is recognized in the fall and noted pharmacist Patrick Tharp has previously presented to the Board on this issue. Ms. Grinston asked the Board about providing suicide prevention and awareness resources in the Board's newsletter or on the Board's website. Ms. Grinston also discussed a potential suicide prevention/awareness webinar. Board consensus to provide resources as suggested.
- DHSS Training: Ms. Grinston has held discussions with Dean Linneman about scheduling a training for DHSS surveyors on Missouri's pharmacy requirements, including, long-term care and sterile compounding issues. Additional information will be provided at a later date.

#D1 Inspection Violation Summary

DISCUSSION: Ms. Grinston presented the inspection violation summary report and indicated the information is based on currently known data. Multiple Board members suggested including the report findings on the Board's website and in future newsletters. Board members commented the report identifies areas where more education may be needed. Ms. Grinston indicated it may be time to consider other outreach tools such as social media and reported she has been in discussions with the Department.

#D2 Best Practices for State Oversight of Drug Compounding

DISCUSSION: Ms. Grinston reported the office continues to review its sterile compounding inspection/investigation procedures and noted multiple inspectors have received additional sterile compounding training. Ms. Grinston reported inspector Katie DeBold is developing a sterile compounding checklist and working with other inspectors to assist with sterile compounding inspections. Ms. Grinston indicated the Board may need to consider how to handle/license non-resident sterile compounders in the future and suggested possibly requiring an inspection either by the Board, NABP or from their home state. Douglas Lang reported other states have increased and expanded their sterile compounding review and noted many states require a state inspection within the last 12-18 months. Mr. Lang reported the current cost for a NABP inspection is approximately \$ 5,000 for a sterile compounding inspection and \$ 3,000 for a non-sterile compounding inspection. Bert McClary, Hospital Advisory Committee Chairman, indicated hospitals are not being meaningfully inspected/surveyed for sterile compounding compliance currently and suggested the Board work with DHSS surveyors. Mr. McClary noted most DHSS surveyors are non-pharmacists. Board consensus to review non-resident sterile compounding issues along with the pending non-resident sterile compounding survey results.

#D3 Collection of Non-Controlled Medication

DISCUSSION: Ms. Grinston reported she has received inquiries from various state entities regarding the proposed rule. Douglas Lang inquired about the mail back provisions in the draft rule and commented the rule should not require mailers to come back to the pharmacy. Mr. Lang noted returned mailers could be sent directly to a reverse distributor. Pamela Marshall asked if the rule clearly addressed how receptacles should be maintained when the pharmacy is closed. Christian Tadrus asked if the rule would allow collection receptacles to be maintained at a non-pharmacy location and also commented the "direct visual observation" requirement may be overreaching. Mr. Tadrus suggested receptacle security could be otherwise addressed (e.g., the receptacle could be permanently affixed within the pharmacy). Bert McClary suggested the Board keep the rule as simple as possible to avoid the unintended consequences of the MTS rule. Mr. McClary noted some licensees have opted out of MTS partially because the rule is too complicated/restrictive. Board consensus to revise the rule based on Board comments and review at a future meeting.

#D5A 2016-2017 Legislation

DISCUSSION: Ms. Grinston provided general legislative updates and reported legislation is moving slowly. The PMP legislation has been assigned to committee for hearing. Ms. Grinston also reported the naloxone bill may pass this year and indicated the Board's fund proposal has been introduced but has not been assigned to committee. Ron Fitzwater reported MPA will be attending a combined hearing in the health committee for several pharmacy related proposals.

#D6A Hospital Advisory Committee

DISCUSSION: Bert McClary provided an update on the Committee's progress and indicated the Committee has met twice since the January Board meeting. Mr. McClary reported the Committee is in the process of reviewing the administration by prescription order rule and is working with Board/DHSS staff on a hospital related webinar. Mr. McClary reported the Committee will be looking at other hospital related issues, such as, expanded technician roles and pharmacy issues related to hospital owned/related care centers (e.g., infusion centers).

#D8A Sterile Compounding Committee Update

DISCUSSION: Christian Tadrus reported the Committee met on April 4th and will meet again on April 6th. Mr. Tadrus indicated the Committee is considering an emergency rule that will provide inspectors more enforcement ability and help close the regulatory gaps until USP Chapter 797 is revised. Mr. Tadrus noted the emergency rule will be presented to the Board for full discussion/approval once finalized.

#D9A Pharmacy Permits

DISCUSSION: Ms. Grinston reported the final order of rulemaking needs to be approved by the Board. Ms. Grinston indicated she has received comments suggesting that the rule retain the language that prohibits dispensing without a valid preexisting patient-practitioner relationship and also retain the language prohibiting dispensing based on an internet-based questionnaire. Christian Tadrus and Barbara Bilek suggested there was value in keeping the language as suggested; Barbara Bilek also suggested prohibiting dispensing based on a telephonic consultation. Additional discussion was held. Ms. Grinston commented the proposed telehealth bill currently pending may address the telehealth/telemedicine issues. **A motion was made by Douglas Lang, seconded by Pamela Marshall, to approve the order of rulemaking with the retention of the internet questionnaire prohibition and the prohibition on dispensing without a valid preexisting patient-practitioner relationship.** Motion passed 4:0:0:1 with roll call vote as follows:

Barbara Bilek – yes	Douglas Lang- yes	Pamela Marshall – yes
Anita Parran – absent	Christian Tadrus – yes	

#C1 Applications for Intern Training Pharmacy Special Site

- GeriCo Pharma
- St. Joseph Regional Medical Center
- Student National Pharmaceutical Assoc.
- IU Health Physicians South
- Peking Union Medical College Hospital

DISCUSSION: Tom Glenski recommended approval of special sites/non-pharmacist preceptors. **A motion was made by Barbara Bilek, seconded by Pamela Marshall,**

to approve all Intern Training Special Site/Non-Pharmacist Applications for 500 hours. Motion passed 4:0:0:1 with roll call vote as follows:

Barbara Bilek – yes	Douglas Lang- yes	Pamela Marshall – yes
Anita Parran – absent	Christian Tadrus – yes	

#C2A STLCOP and UMKC College of Pharmacy

- UMKC Site List
- UMKC Preceptor List
- STLCOP Site List
- STLCOP Preceptor List

DISCUSSION: Tom Glenski recommended approval of the school lists as presented. A motion was made by Barbara Bilek, seconded by Christian Tadrus, to approve the site/preceptor lists as recommended. Motion passed 4:0:0:1 with roll call vote as follows:

Barbara Bilek – yes	Douglas Lang- yes	Pamela Marshall – yes
Anita Parran – absent	Christian Tadrus – yes	

#A3 General Administration Report (Cont'd)

DISCUSSION: Kimberly Grinston reported Tammy Siebert has announced her retirement. The Board thanked Ms. Siebert for her service and presented her with a retirement gift.

MOTION TO CLOSE 11:19 A.M.

At 11:19 a.m., Pamela Marshall made a motion, seconded by Christian Tadrus, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13), (14), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 4:0:0:1 with roll call vote as follows:

Barbara Bilek – yes	Douglas Lang- yes	Pamela Marshall – yes
Anita Parran – absent	Christian Tadrus – yes	

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT APPROXIMATELY 11:20 A.M.

RETURN TO OPEN

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 2:12 p.m.

MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM AT APPROXIMATELY 2:12 P.M.

#B3 James Williams, #029907, #2014-003538

ITEMS ENCLOSED:

- Notice of Disciplinary Hearing
- Complaint
- Administrative Hearing Commission Default Decision
- Consent Order

DISCUSSION: The Board convened a disciplinary hearing at 2:16 p.m. for James Williams. Mr. Williams was present without counsel; Joshua Hill appeared on behalf of the Board. Mr. Williams and Mr. Hill provided opening statements. Mr. Williams was sworn in and testified on his behalf. Mr. Hill presented no witnesses but admitted Exhibit 1 without objection. Mr. Williams offered Exhibit A which was objected to as hearsay. After further testimony by Mr. Williams, the objection to Exhibit A was withdrawn and Exhibit A was admitted. Board members questioned Mr. Williams. Mr. Williams indicated the Kansas Board of Pharmacy placed him on probation for five (5) years and stated he is a full-time floating pharmacist for Genoa in both Missouri and Kansas. Mr. Hill and Mr. Williams provided closing statements. The hearing adjourned at 2:57 p.m. A transcript of the hearing is available in the Board's records.

#B4 Michael Jones, #045077, #2013-006818

ITEMS ENCLOSED:

- Notice of Felony Disciplinary Hearing
- Felony Conviction Complaint

DISCUSSION: The Board convened a disciplinary hearing for Michael Jones at approximately 3:00 p.m. Mr. Jones was present without counsel; Cotton Walker appeared on behalf of the Board. Mr. Jones and Mr. Walker provided opening statements. Exhibits 1 and 2 were offered into evidence by Mr. Walker and admitted without objection. Mr. Jones was sworn in and testified on his behalf; Mr. Jones indicated he is currently on criminal probation for three (3) years. Exhibit A was offered into evidence by Mr. Jones and admitted. Mr. Walker cross-examined Mr. Jones. Questions were received from Board members. Mr. Walker requested to amend the complaint by interlineation. Mr. Walker and Mr. Jones provided closing statements. The hearing adjourned at 3:51 p.m. A transcript of the hearing is available in the Board's records.

MOTION TO CLOSE 3:51 P.M.

At 3:51 p.m., Christian Tadrus made a motion, seconded by Douglas Lang, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13), (14) and (17), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 4:0:0:1 with roll call vote as follows:

Barbara Bilek – yes
Anita Parran – absent

Douglas Lang- yes
Christian Tadrus – yes

Pamela Marshall – yes

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT APPROXIMATELY 3:51 P.M.

RECONVENE OPEN 11:55 A.M.
WEDNESDAY, APRIL 6, 2016

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 11:55 a.m. on April 6, 2016.

#D4A 2016-2017 Legal Contracts

DISCUSSION: Ms. Grinston reported Curt's legal contract has been submitted for review/approval with a requested rate increase. Board members asked if the requested rate was comparable to rates paid for other Board legal services and commented the Board should ensure the rates are consistent. Ms. Grinston indicated she will provide other legal fee rates once new contracts are submitted. A motion was made by Douglas Lang, seconded by Pamela Marshall, to approve Curtis Thompson's legal contract and to review the applicable rate after other attorney contracts have been submitted. Motion passed 4:0:0:1 with roll call vote as follows:

Barbara Bilek – yes Douglas Lang- yes Pamela Marshall – yes
Anita Parran – absent Christian Tadrus – yes

THE FOLLOWING ITEMS WERE REVIEWED IN SECTION E, WHICH REQUIRED NO ACTION OR DISCUSSION.

#E1 Licensees Presently Under Discipline

- Pharmacists
- Pharmacies
- Drug Distributors
- Pharmacy Technicians – Conditional Registration
- Pharmacy Technicians – Employment Disqualification List

#E2 Brehe V. MO Dept. of Elementary Secondary Education

- MO Court of Appeals, Western District Decision

#E3 Massachusetts Opioid Restrictions

#E4A APhA 2015 Annual Report

#E5A Board Licensee Statistics

MOTION TO ADJOURN 11:56 A.M.

At approximately 11:56 a.m., a motion was made by Pamela Marshall, seconded by Barbara Bilek, to adjourn the April 5-6, 2016 meeting. Motion passed 4:0:0:1 with roll call vote as follows:

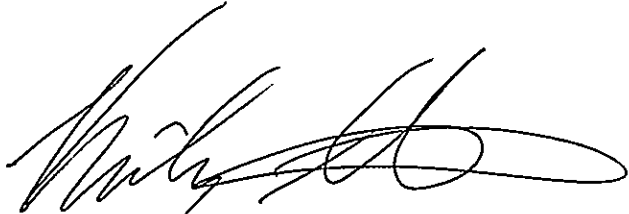
Barbara Bilek – yes

Douglas Lang- yes

Pamela Marshall – yes

Anita Parran – absent

Christian Tadrus – yes

A handwritten signature in black ink, appearing to read 'Kimberly A. Grinston', written over a horizontal line.

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

DATE APPROVED: 10/26/2016